"Improvements in Medical Device Packaging"

FIELD OF THE INVENTION

The present invention relates to a medical device package and in particular to a catheter guide wire packaging device.

BACKGROUND OF THE INVENTION

Such guide wire packaging devices generally comprise a thermoplastic tube having a bore for reception of the wire and some means for securing the packaging device in position by spirally winding it around itself and securing it together. This latter form of packaging device is extensively used and has many advantages in that the coil formed by the packaging device containing the wire can be held firmly together and there is no overlapping of the wire onto itself. There is no internal contact of the wire coils so that there would be no surface damage or contamination and finally if the packaging device is manufactured from a low friction material such as polyethylene, damage is virtually eliminated during handling. This is the type of packaging used for the majority of medical guide wires sold at present.

When it is considered that nearly 10 million units of guide wires are sold every year and guide wires are relatively delicate instruments, it can be appreciated that anything that can reduce the cost of packaging the guide wires and, at the same time, provide a more efficient packaging, is of considerable importance. Thus, while the present guide wire packaging device, often referred to as a guide wire dispenser, has been on the market for several years and performs the task adequately, it is not optimal.

One of the important features in the design of such a guide wire packaging device and in particular a packing device for catheter wires is that it is essential that when wound, the diameter of the innermost coil of the spiral hoop so formed is not so small as to allow the wire to set into a particular configuration or deform by kinking. There is thus a minimum internal diameter to which the guide wire dispenser's innermost

coil can be formed. The outside diameter of the final assembly is dependent on this minimum internal diameter, the length of the tube and the magnitude of the gap between the coils. The length of the guide wire can be as much as 300 cm and the gap between the coils of most present constructions is 2 mm.

At the same time, there are some disadvantages in the present construction of catheter wire dispenser in that they are relatively expensive to produce and as there are a large number of components, assembly is expensive and time consuming.

The present construction of catheter wire dispenser incorporates a fastener snap-fit mount which does not consistently hold the coils in an ideal configuration. Adjacent coils in an assembly can slide and rotate relative to one another. This gives the coils 2 degrees of freedom in respect of available movements. If the coils slide relative to one another, then the gap between the coils will vary throughout the assembly from as little as 0 mm to as much as 10 mm or 15 mm. If the coils rotate in the snap-fit mount, then the planarity of the assembly is lost. One of the negative affects of these movements is that the volume occupied by the package is large and variable. Another disadvantage of these movements is that they put stress on the snap-fit mount joints and these frequently fail under load with the result that the guide wire dispenser is presented to the physician in an undesirable configuration. Ideally such a catheter wire dispenser would use the minimum amount of plastics and have less bulk construction of dispenser.

In the prior art US Patent No. 5, 366, 444 discloses a hand operated guide wire advancement device in which an outer tube containing a guide wire is held in a coiled position by two or more spaced-apart clips which are releasably engagable with adjacent coils of the tube. In US Patent Specification No. 5, 525, 178 there is disclosed a method for binding elongate sections of tubular hosing or piping in a coiled configuration in which a bead of adhesive is applied to an exterior of the tube to join adjacent coils of the tube. This provides a weak bond such that a leading portion of the tube can be pealed away from the coil when required for use.

A further problem with the present construction of guide wire packaging is the necessity to provide the attachment of the hoop to a fluid flushing device such as a

syringe. Such fluid flushing devices are required to ensure that prior to use, the guide wire can be washed in saline or some other solution. This is usually achieved by flushing fluid through the packaging tube. It is therefore necessary to connect the tube to a fluid dispensing device and this is achieved by attaching a luer to the end of the guide wire packaging device.

A significant disadvantage of the present construction of luer is that it does not grip the tube sufficiently tightly to prevent rotation as the fluid flushing device is being screwed into position.

It is an object of the present invention to provide an improved construction for medical device packaging and in particular to providing a catheter wire dispensing device.

It is another object of the invention to provide an adapter for connecting such a guide wire packaging device to a flushing device.

SUMMARY OF THE INVENTION

According to the invention, there is provided a packaging device for an elongate flexible medical device such as a guide wire, a catheter or the like, the packaging device including a flexible elongate body having means for reception of the medical device, and engagement means to allow interengagement of adjacent portions of the body when the body is wound in a coiled configuration to retain and support the body in said coiled configuration, characterised in that the engagement means is integrally formed with the flexible elongate body.

It will be appreciated that an advantage of this arrangement is that since the flexible elongate body can be wound closely to itself, that the packaging will be much smaller than heretofore has been possible with currently available devices.

In one embodiment of the invention the engagement means comprises complementary interengagable formations on the flexible elongate body.

In another embodiment the complementary interengagable formations comprise

elongate elements on an exterior of the body which extend substantially parallel to a longitudinal axis of the body.

In another embodiment the complementary interengagable formations are resiliently deformable for interengagement.

In another embodiment the engagement means is operable to support coils of the body side by side in a common plane.

In a further embodiment the formations are interengagable in a direction substantially parallel to a plane defined by the coiled elongate body. That is they interengage in a direction substantially parallel to a line interconnecting centres of adjacent coils.

In an alternative arrangement the formations are interengagable in a direction which is at an angle to a plane defined by the assembled coil. In another embodiment the formations may be interengagable in a direction which is normal to a plane defined by the assembled coil.

Ideally, the engagement means comprises male and female cooperating members.

A further advantage is that if the male and female engagement means project around the whole of the tube, this means that the hoop so formed when the tube is spirally wound will maintain its planarity at all times and further will allow that the product be presented to the physician in the correct configuration at all times and as a medical product, this is an important consideration.

A further advantage of the male and female engagement means is that there is no degree of freedom of movement available to coils relative to one another and thus the space occupied by a guide wire packaging assembly is constant, even if the package comes under the influence of handling loads.

A further advantage of the device is that since the hoop is comprised of only one component, the assembly of the guide wire packaging devices according to this invention can be carried by machinery in an automated fashion.

In one embodiment of the invention, the male and female members are alternatively arranged around the periphery of the tube. The male and female members are preferably arranged on opposite sides of the tube. This is a particularly suitable configuration. For example, in one embodiment of the invention, there is one set of male members and one set of female members on radially opposite sides of the tube. Ideally, there is a pair of male members and a pair of female members in each set.

In one embodiment of the invention, the engagement means comprises a longitudinally arranged groove and a radially opposite, longitudinally arranged upstanding rib on the tube, the upstanding rib being dimensioned to form a force-fit within the groove.

In a preferred embodiment of the invention, the groove is re-entrantly shaped. This particularly simple construction will be more than adequate in many situations.

In another embodiment each male member comprises a projection extending outwardly of the elongate body and each female member is formed by an arm projecting outwardly from the elongate body to define a socket therewith for reception of the male projection.

In another embodiment each male projection is formed by a rib extending between opposite ends of the elongate body and each arm forming a female member extends between opposite ends of the elongate body.

In another embodiment each arm is of arcuate section.

In a further embodiment each male member has a bulbous head and the female member comprises a reentrant slot for snap engagement with the associated male projection.

In another embodiment the male and female members are formed by curved arms at opposite sides of the body, each arm terminating in a bulbous head forming the male member, and the arm defining with the elongate body a female socket for reception

of the bulbous head.

In another embodiment the male formations comprise a pair of spaced-apart projections extending outwardly at one side of the elongate body and the female formations comprise an associated pair of arms projecting outwardly at an opposite side of the elongate body to define sockets therewith for reception of the associated pair of male members.

In a further embodiment the arms extend tangentially outwardly at opposite sides of the elongate body and are substantially parallel, each arm terminating in an inturned lip to define with the body and the arm a female socket for reception of an associated male projection.

Conveniently the elongate body may be a profiled extrusion.

In another embodiment the elongate flexible body is made from a polymeric material.

In another embodiment the elongate flexible body is made from a thermoplastics material.

In a further embodiment the elongate flexible body is made from a polyolefin, a fluoropolymer or a polyamide material.

In another embodiment the means for reception of the medical device is an elongate lumen within the body. The body is essentially tubular.

In another embodiment the engagement means is operable to retain the elongate body in a coiled configuration in which the distance between adjacent lumen sections is less than the diameter of the lumen.

In a still further embodiment of the invention, there is provided an adapter for connecting the tube to a fluid flushing device comprising:

a body member;

connectors in the body member engaging with the fluid flushing device;

a bore in the body member for alignment of the bore with the tube;

reception means in the body member for the engagement means to lock the wire packaging device within the adapter.

In a further embodiment of the invention, the thread and luer lock taper for attachment of the fluid flushing device is integrated into the end of the tube of the medical packaging device. This construction is achieved by forming the thread and taper on the end of the tube. This is a particularly suitable configuration as it overcomes all the issues of rotation and leakage.

Ideally the fluid flushing is achieved by using an ANSI luer connection. The particular advantage of the present invention is that it overcomes the problems of more conventional connection devices when difficulties are often encountered when trying to lock the adapter on the tube. This specifically refers to rotation of the conventional luer attached to the dispenser being loaded rotationally during the connection of a syringe or other device.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which:

Fig. 1 is a perspective view of portion of a medical packaging device;

Fig. 2 is a typical cross-sectional view of the medical packaging device of Fig. 1;

Fig. 3 is a side view of the medical packaging device of Fig. 1 and 2;

Fig. 4 is a cross-sectional view along the lines IV-IV of Fig. 3;

Fig. 5 is a side view of an adapter for use with the invention;

Fig. 6 is a cross-sectional view of the adapter of Fig. 5;

Fig. 7 is a typical cross-sectional view through the adapter of Fig. 5 when assembled on a tube of a medical packaging device according to the invention;

Fig. 8 is a typical cross-sectional view of an alternative construction of adapter according to the invention;

Fig. 9 is a sectional view through the adapter of Fig. 8 mounted on a medical packaging device according to the invention;

Fig. 10 is a view similar to Fig. 9 of an alternative construction of adapter;

Fig. 11 is a view similar to Figs. 9 and 10 of a still further construction of adapter according to the invention;

Fig. 12 is a cross-sectional view of an alternative construction of medical packaging device;

Fig. 13 is a cross-sectional view of a further alternative construction of medical packaging device;

Fig. 14 is a cross-sectional view of another construction of medical packaging device;

Fig. 15 is a cross-sectional view of a further construction of a medical packaging device;

Fig. 16 is a cross-sectional view of another construction of a medical

packaging device;

Fig. 17 is a cross-sectional view of another medical packaging device; and

Fig. 18 is a cross-sectional view of another medical packaging device.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring to the drawings and initially to Figs. 1 to 4 thereof, there is provided a medical packaging device according to the invention, indicated generally by the reference numeral 1, comprising an elongate body formed by a flexible tube 2 of a plastics material having a bore 3 for reception of a catheter wire, indicated in the drawings by the reference numeral 4. Mounted on the exterior surface of the tube 2 is an engagement means provided by a pair of spaced-apart male members 5 and complementary female members 6. The male members 5 form ribs extending between opposite ends of the tube 2 and the female members 6 are formed by arcuate arms 7 which also extend the length of the tube 2. These arms 7 define female sockets 8 for reception of the male members 5.

In use, when a catheter wire 4 is placed within the bore 3 and the tube 2 is wound around itself, as illustrated in Fig. 3, the male members 5 engage the female members 6 and the medical packaging device 1 is locked in a coiled position, as illustrated clearly in Fig. 4.

Referring to Figs. 5 and 6, there is illustrated an adapter for connecting the medical packaging device 1 of Figs. 1 to 4, to a luer fluid flushing device. The adapter is indicated generally by the reference numeral 10 and comprises a body member 11 terminating at a proximal end in a threaded head 12 for connection to the luer device and having a tapered bore portion 13 connecting with a lumen 14 and then an enlarged stepped bore portion 15 for reception of a tube 2. At a distal end 18 of the body member 11, there is provided four spaced-apart slots 16 which extend in an axial direction inwardly from the end of the body members 11 for reception of the male members 5 and female members 6, as can be seen in Fig. 7.

It will be noted that an inner end of the bore portion 15 terminates in an annular recess 17 for reception of an end face of the tube 2.

It will be appreciated that with this embodiment of the invention, that by a careful use of the correct dimensions, the female members 6 may be used to secure the tube 2 firmly to the body member 11 through the slots 16. Similarly, the male members 5 may perform the same task. The advantage is that both the male and female members being of plastics materials will deform relatively easily and thus the manufacturing tolerances for the adapter 10 do not have to be high.

Alternatively, either the male or female members could be formed with some form of interference fit to secure the adapter 10 more securely to the medical packaging device 1.

As an alternative, if the bore portion is correctly dimensioned relative to the tube 2, the necessary force-fit can be achieved.

Referring to Figs. 8 and 9, there is illustrated an alternative construction of adapter, indicated generally by the reference numeral 20. Parts similar to those described with reference to the previous drawings are identified by the same reference numerals. In this embodiment, there is provided a bore portion 15 in the bore of the adapter 20 which is so arranged as to receive all of the tube 2, as can be seen clearly from Fig. 9.

Referring to Fig. 10, there is illustrated a further construction of adapter, indicated generally by the reference numeral 25. Parts similar to those described with reference to the previous drawings are identified by the same reference numerals. In this embodiment of the invention, the adapter 25 is provided with external lugs or protrusions 26 to facilitate the gripping of the adapter 25.

Fig. 11 illustrates a still further construction of adapter, indicated generally by the reference numeral 27. Parts similar to those described previously are assigned the same reference numerals. In this case the adapter 27 has a body member 28 having opposed external flat surfaces 29 to facilitate gripping.

In another embodiment, the threaded head 12 and the tapered bore portion 13 of the adapter body may be formed on the end of the tube 2 of the medical packaging device. This eliminates the need for a separate adapter while still facilitating the attachment of a flushing device.

Referring to Figs. 12 to 16, there are shown a series of alternative constructions of medical packaging device. Parts similar to those described previously are assigned the same reference numerals.

Referring now to Fig. 12, there is shown an alternative construction of medical packaging device indicated generally by the reference numeral 30. Parts similar to those described previously are assigned the same reference numerals. In this case the arms of the female members 6 are formed by tangential flanges 31 which extend outwardly at opposite sides of the tube 2 and are substantially parallel. An inturned lip 32 is provided at an outer free end of each flange 31 to define with the tube 2 and flange 31 a socket 33 for reception of the male member 5.

Referring to Fig. 13, there is shown an alternative construction of medical packaging device 40 in which a single male member 41 engages in two female members 42. A further feature of this construction is the creation of a second lumen or bore 3. This facilitates the protection of a second medical device within the one configuration.

Referring to Fig. 14, there is shown an alternative construction of medical packaging device 50 in which the male members 5 and female members 6 are spaced wider apart.

Referring to Fig. 15, there is shown an alternative construction of medical packaging device, indicated generally by the reference numeral 60 having male members 65 and female members 66 which are rounded. In this construction, it can be appreciated that the male members 65 and female members 66 can be so dimensioned as to make disassembly difficult during shipping and handling. This rounded construction has the advantage of making manufacture of the medical packaging device 60 easier. It will also facilitate disassembly of the device 60 if

enough force is applied.

Referring to Fig. 16 there is shown an alternative construction of medical packaging device 70 in which the engagement means comprises male and female cooperating members which form a finger lock mechanism. An arcuate male flap 75 defines with the flexible tube 2 a female socket 76 for reception of a bulbous head 77 of the male flap 75.

Referring to Fig. 17 there is shown another alternative construction of medical packaging device indicated generally by the reference numeral 80. Parts similar to those described previously have been assigned the same reference numerals. In this case the engagement means comprises a male bead or rib 81 at one side of the tube 2 and a complementary pair of arms or flaps 83 at an opposite side of the tube 2 for snap engagement with the rib 81 on the next adjacent coil of the tube 2 to interconnect the tube coils.

Referring now to Fig. 18 there is shown another arrangement of medical packaging device indicated generally by the reference numeral 90. In this case interengagement of coils of the tube 2 is affected by a pair of outwardly extending resilient flaps 91 which define the female member which embraces an exterior of the next adjacent tube 2 coil portion. So, in this case, the tube 2 itself effectively forms the male portion and the flaps 91 form the complementary female portion of the engagement means. The arms formed by the flaps 91 extend beyond the equator of the tube 2 in order to hold the tube and may extend as far as the flaps 91 on the next adjacent coil of the tube 2.

It will be appreciated that the various engagement means described above may be adapted such that the force required to interlock the engagement elements is less than the force required to unlock the engagement elements. It will also be noted that the tubular elongate body forms a spiral hoop in the wound interlocked configuration. Typically the tube is wound on itself multiple times. It will be noted that the tubular elongate element is interlocked at each point of contact. The tubular element is neatly and tightly wound about itself and ideally the distance between adjacent lumen segments in the wound configuration is less than the diameter of the lumen. When in

the wound configuration the package comprises a generally circular or elliptical shape.

The invention is not limited to the embodiments hereinbefore described which may be varied in both construction and detail within the scope of the appended claims.